

REMARKS

By this Amendment, Applicants herein amend the claims in a manner so as to overcome objections of the Examiner with regard to claim language and to more particularly point out the patentable features of the claims. Claims 4 and 5 have now been canceled, and new Claims 21-27 have been added which are directed to subject matter supported in the original application. Specifically, the amendments to Claim 1 have been made to point out that the serum albumin compositions of the application are specifically designed to be absorbed into the skin or hair, such as disclosed in the original specification, e.g., at Page 5, lines 4-8. In addition, new Claims 21-26 reflect certain modified forms of albumin as disclosed in Applicant's co-pending patent application, Serial No. 09/616,962, which was incorporated by reference in the present application at Page 7, lines 11-13. Finally, new Claim 27 represents a combination of the subject matter of Claim 3 with the original Claim 1, and since Claim 3 was determined by the Examiner to be patentable over the cited prior art, Claim 27 is likewise patentable.

Accordingly, the present amendments to the claims, and the insertion of the Sequence Listing necessitated thereby, do not add any new matter to the present application. Claims 1-3, 6-12, 14, 15, and 17-27 are now pending following the present amendment, and for the reasons as stated below, Applicants submit that the present claims now overcome all previous objections and have been placed in condition for immediate allowance.

In the Official Action, the Examiner objected to Claims 1, 3-5, 15 and 19-20 under 35 U.S.C. §112, first paragraph, in that while these claims were considered

enabled for an "unmodified" albumin-based composition, they were not considered enabled "based on a bio-engineered human serum albumin." See Official Action, page 2-3. The Examiner then went on for the next six pages to provide an elaborate discussion of why he did not believe that Claims 4 and 5 were enabled as defined. However, the Examiner's arguments regarding non-enablement were solely to Claims 4 and 5 and did not relate in any manner to independent Claim 1 which is clear on its face with regard to the description of normal human serum albumin, a known protein as explained further below. Accordingly, it is not seen how the language of Claims 4 and 5 reflects in any manner on the enablement of Claim 1 which is clear on its face and would be readily understood and practiced by one of ordinary skill in the art. In any event, the Examiner's objections regarding enablement have now become moot by the cancellation without prejudice of Claims 4 and 5.

In addition, to the extent that the Examiner asserted that the claims of the present application other than Claims 4 or 5 were somehow not enabled because "the sequences themselves are required" (see Official Action, page 3), this objection is traversed in that Applicant in fact disclosed the sequence of human serum albumin in patents incorporated by reference in the specification, such as U.S. Pat. No. 5,780,594, which discloses the precise sequence of human serum albumin. See specification at page 7, lines 4-8. Accordingly, the human serum albumin as described in Claim 1 is the protein having the known human serum albumin sequence, and this actual protein can either be isolated in natural form, or, as disclosed repeatedly in Applicants' specification, can be produced through recombinant means, which is the preferred form of the invention. In any event, the skilled practitioner would readily be enabled by the

specification to make and use the composition as described in the present Claim 1, and thus in light of the cancellation of Claims 4 and 5, the only claims for which the Examiner made specific arguments for non-enablement, the Examiner's rejection under 35 U.S.C. §112 on the basis of enablement is respectfully traversed.

In the Official Action, the Examiner had various objections to the claims on the basis of 35 U.S.C. § 112, second paragraph, but these objections have been overcome in light of the present amendments. Accordingly, the claims of the present application are clearly proper under 35 U.S.C. §112, and any objections on the basis of this provision are respectfully traversed.

In the Official Action, the Examiner rejected Claims 1-2, 6-12, 14 and 17-18 under 35 U.S.C. §102(b) as being anticipated by Kligman European patent application no. 244,859. Accordingly, the Examiner recognized that at minimum, the subject matter of the remaining claims was not anticipated or made obvious by any prior art reference. Moreover, for reasons as set forth in more detail below, it is clear that the Kligman reference does not disclose or suggest the **absorbable** serum albumin composition of the present claims, and thus the Examiner's rejection on the basis of this reference, insofar as applied to the claims as amended, is respectfully traversed for the reasons as explained more fully below.

The presently claimed invention relates to a novel serum albumin composition which can be used to enhance cleansing or conditioning of the skin and hair because it acts to be absorbed in the skin or hair so as to replace or replenish the human serum albumin that naturally resides there. This feature of the claimed compositions, namely that they are designed to be absorbed in the skin or hair, clearly distinguishes these

compositions from Kligman which merely discloses the use of a combination of albumin and sodium silicate in a dried film which stretches out over the skin and does not get absorbed therein. In fact, because the silicate composition in Kligman is designed to be dried out so as to form a film which stretches out over the skin and actually lifts the skin up, it acts in an entirely different manner than absorbable serum albumin compositions of the present invention and thus prevents moisture from being absorbed therein and instead removes moisture from the skin. In sharp contrast, the presently claimed compositions indeed not only replenish the natural serum albumin in the skin or hair but indeed pull moisture into the skin, and thus act to moisturize and/or condition the skin or hair being treated.

Even further, it appears that the composition in Kligman was based on the old home remedy against wrinkles wherein egg white was applied to the skin and left to dry. In fact, Kligman refers to the prior art which showed that "[a]lbumin from whites of eggs has been incorporated as an active ingredient in facial cosmetic materials." Page 1, line 1. However, Kligman was erroneous in describing the whites of eggs as "albumin" when in fact this protein from eggs is called albumen and is **not** the same protein as serum albumin (human or otherwise) as employed in the present invention. Based on this premise, the serum albumin as disclosed in the Kligman patent is thus not absorbed into the skin as in the present invention, but is instead used as a matrix which dries on the skin and allows for the cosmetics to be applied over the dried film.

It is thus the case that Kligman does **not** disclose or suggest the present compositions which are designed to be absorbed into skin or hair so as to replace or replenish the natural serum albumin present in those tissues and actually pull moisture

into the skin as opposed to the dried Kligman compositions which act in the opposite manner. Applicant thus submits that the Kligman reference does not anticipate or make obvious the invention as presently claimed, and that the Examiner's rejection on the basis of this reference should be withdrawn.

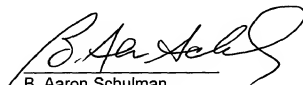
With regard to new claims 21-27, Claims 21-26 relate to the compositions of the invention wherein the serum albumin is modified in the ways as set forth in those claims, and new Claim 27 reflects the composition of the invention wherein recombinant serum albumin is used. In all of these cases, the Examiner did not locate any prior art references which disclosed or suggested this subject matter, and thus since the claims are in all respects proper under 35 U.S.C. § 112, it is submitted that these claims are patentable as well.

In light of the foregoing amendments and arguments, Applicant submits that the present application overcomes all prior objections, and is now in condition for immediate allowance. Such action is earnestly solicited.

Respectfully submitted,

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ATTACHMENT A

Marked Up Amended Claims

Following herewith is a marked up copy of each amended and new claim.

1. (Amended) A hypoallergenic skin or hair treating composition for absorption into the skin or hair comprising human serum albumin in an amount effective to be absorbed into the skin or hair so as to replenish the structure of these tissues, enhance cleansing, conditioning, or other beneficial cosmetic or dermatological purpose for skin or hair and a suitable cleansing, conditioning, cosmetic or dermatological agent, vehicle, carrier or excipient.

4. Canceled.

5. Canceled.

7. (Amended) A composition according to claim 76 wherein the serum albumin comprises 1 to 10 mg/ml of the liquid soap.

9. (Amended) A composition according to claim 98 wherein the glycerin solution comprises a 10-60% glycerin solution.

11. (Amended) A composition according to claim 98 wherein the serum albumin in the glycerin solution is at a concentration in the range of about 1 to 250 mg/ml.

12. (Amended) A composition according to claim 98 wherein the serum albumin in the glycerin solution is at a concentration of about 40 mg/ml.

17. (Amended) A hypoallergenic skin or hair treating composition according to Claim 1 comprising 1-60 mg/ml human serum albumin dissolved in a 40-60% glycerin solution.

21. (New) A composition according to claim 1 wherein the serum albumin is modified at the N-terminal end so that the sequence begins with Lys-Ser-Glu.

22. (New) A composition according to claim 1 wherein the serum albumin is modified at the N-terminal end so that the sequence begins with Ala-His-Lys-Ser-Glu (SEQ ID NO: 1).

23. (New) A composition according to claim 1 wherein the serum albumin is modified at the N-terminal end so that the sequence begins with His-Lys-Ser-Glu (SEQ ID NO: 2)

24. (New) A composition according to claim 1 wherein the serum albumin is modified at the N-terminal end so that the sequence begins with Asp-Ala-His-Lys-Ser Glu (SEQ ID NO:3).

25. (New) A composition according to claim 1 wherein the serum albumin is modified at the N-terminal end so that the sequence begins with Asp-Ala-Xaa-Lys-Ser-Glu (SEQ ID NO: 4).

26. (New) A composition according to claim 1 wherein the serum albumin is modified at the N-terminal end so that the sequence begins with Glu-Ala-Glu-Phe-Asp-Ala-His (SEQ ID NO: 5).

27. (New) A hypoallergenic skin or hair treating composition comprising recombinant human serum albumin in an amount effective to enhance cleansing, conditioning or other cosmetic or dermatological purpose for skin or hair, and a cleansing, conditioning, cosmetic or dermatological agent, vehicle, carrier or excipient.